

### REMARKS

This Amendment is made in response to the Office Action dated October 6, 2003. The Examiner has rejected each of pending claims 1 through 22 based on 35 U.S.C. §103. Applicants respectfully traverse each of these rejections pursuant to the enclosed remarks. Applicants also submit new claims 23 through 28 for consideration. These claims are submitted to highlight the novel combination of features of Applicants' invention.

The Examiner has rejected each of claims 1 through 22 based on non-obviousness over Application No. US2002/0000253/A1 to Fillmore et al. ("the Fillmore Application") in view of U.S. Patent No. 4,801,292 to Watson ("the Watson Patent). However, neither of these patents, either separately or in combination, teach the novel arrangement or overall function of Applicants' flush tool. It is this arrangement and function of Applicants' invention that Applicants have claimed and assert are novel.

Furthermore, the Examiner has not cited to any teaching or motivation to combine the disclosure of the Fillmore Application with the disclosure of the Watson Patent. Applicants' flush tool functions in a novel manner unknown in the prior art. Therefore, even if the disclosure of the Fillmore Application could be combined with the disclosure of the Watson Patent to form the Applicants' claimed invention (which they cannot), there is no motivation or teaching within any prior art reference to combine the features as claimed.

Applicants have reviewed the art cited by the Examiner and believe that each of the rejected claims is patentable over any possible combination of these references. As individually indicated below, each of these claims contains elements not found in either the disclosure of the

Fillmore Application or the Watson Patent. Furthermore, Applicants' invention arranges the claimed elements in ways not foreseen by those references or the prior art in general.

As described by the Examiner, the Fillmore Application describes a typical flush tool well-known in the prior art. Thus, the Fillmore Application describes a flush tool comprising a passageway having an access port and a mechanism associated with the access port for providing selective fluid communication with the passageway. The only function of the flush tool disclosed in the Fillmore Application is to control flow of fluids from the access port to the passageway.

The Watson Patent describes a simple pump in combination with a medical filter. The valve mechanisms cited by the Examiner are arranged to control the direction of flow through the pump. These valves operate in unison. One valve is always open while the other is closed and vice versa. Furthermore, the valves of the pump disclosed in the Watson Patent are arranged such that they are not selectively controlled. Instead they are controlled by the forces of the fluid flow.

The flush tool of the present invention provides a novel function and a novel arrangement of components to achieve that function. In a preferred embodiment, this invention provides for a flush tool which can accommodate a medical catheter disposed entirely within its first tube, seal about the catheter at both the proximal and distal ends of the first tube, and then provide for pressurized fluid to be introduced into the catheter and flush tool system. This operation is especially useful in flushing a catheter through a side port in the catheter. The components of the present invention are therefore arranged in a novel manner to perform this and other functions. Each of the following claims is therefore distinct from the prior art, including those references cited by the Examiner. Each of these claims should therefore be reconsidered and allowed.

### Claim 1

Claim 1 not only claims a flush tool with two valves, it identifies the novel arrangement of those valves. The use of valves at both the proximal and distal ends of the first tube enables the flush tool to seal off the first tube entirely or selectively at both ends. The valve disclosed in the Fillmore Application is arranged to provide fluid communication between the access port and the passageway. The valves disclosed in the Watson Patent operate only in unison and are not configured to entirely seal off the passageway. The novel arrangement of the tubes and valves as claimed in claim 1 are unknown in these and other prior art references. Applicants therefore respectfully traverse the Examiner's rejection based on the Fillmore Application in light of the Watson Patent and urge the Examiner to reconsider and allow this claim.

### Claim 2

Dependent claim 2 adds additional elements to novel claim 1. The ability of the valves to sealably engage a catheter is not disclosed by the Fillmore Application or the Watson Patent either singly or in combination. The simple valves described in the Watson Patent preclude the use of catheters passing through the valves. Such valves would not be able to function with catheters disposed through them. The Watson Patent therefore teaches against any combination of references that would require sealable engagement with a catheter. This claim should be allowed both as being dependent on independent claim 1 and as claiming novel features of the valves.

### Claims 3-11

Each of dependent claims 3 through 11, claim further elements of Applicants' invention in addition to the elements of claim 1. The novel features of these claims are not explicitly mentioned in the Examiner's rejection. Nor do any of these novel combinations appear in the art cited by the Examiner. Claims 3 through 7, claim a particular arrangement of the two valves which allow for selectively sealing and unsealing those valves by a slidably engaged actuating member. Claims 8 and 9, claim a different arrangement of the valves which allow for selectively sealing and unsealing those valves by a rotatably engaged actuating member. Claim 10 claims the use of transparent material. Claim 11 claims a means for attaching a fluid source to the flush tube. Each of these claims are dependent on novel claim 1 and provide further elements to that claim. Each of these claims should be reconsidered and allowed.

### Claim 12

Claim 12 claims a novel catheter and flush tool system for the preferred function of evacuating air from the auxiliary lumen of the catheter. Regardless of whether any of the passageways disclosed in the Fillmore Application or the Watson Patent, may be considered equivalent of a catheter, neither of these references disclose, teach or suggest "a catheter having an auxiliary lumen." Moreover, the claimed arrangement of the flush port and catheter system provides abundant reason for allowance of this claim. The combination of the disclosure in The Fillmore Application and the disclosure in the Watson Patent neither teaches a tool configured to be "mounted on the catheter" nor fluid-tight seals that are capable of being "sealed about the catheter." For at least these reasons, Applicants respectfully traverse the Examiner's rejection and urge the Examiner to reconsider and allow this claim.

### Claims 13-18

Each of dependent claims 13 through 18 claim further features and elements in addition to those claimed in novel claim 12. These features are not explicitly addressed in the Examiner's rejection. Claim 13 adds removability of the flush tool from the catheter. Claim 14 adds a guide wire to the system. Claim 15 adds an intraluminal device to the system. Claim 16 adds a syringe to the system. Claim 17 adds repeatable sealing and unsealing of the valves. Claim 18 adds the use of vacuum pressure to flush the system. Each of these claims should be allowed as dependent on novel claim 12 and for adding further elements and features to the novel system.

### Claim 19

Claim 19 claims "a method of flushing air from the guide wire lumen of a rapid exchange catheter." This novel method is not specifically addressed in the Examiner's rejection. Neither of the devices disclosed in the Fillmore Application nor the Watson Patent, either singly or in combination, are capable of performing this method. The steps of this method can be performed only with the novel flush tool disclosed in this Application. Moreover, "placing a flush tool over the catheter," and "sealing the flush tool to the catheter" are functions not considered or disclosed by the prior art. Therefore, Applicants respectfully traverse the Examiner's rejection and urge the Examiner to reconsider and allow this claim.

### Claims 20-22

Dependent claims 20 through 22 add additional steps and features to the novel method of claim 19. These claims and their additional steps and features have not been specifically

addressed by the Examiner. Claim 20 adds an additional step of "introducing pressurized fluid into the flush port." Claim 21 adds a "guide wire disposed throughout the guide wire lumen." Claim 22 adds the use of an introducer sheath. Each of these claims should be allowed as dependent on novel claim 19 and for adding further steps and features to the novel system.

#### New Claim 23

Applicants have added new claim 23 to highlight the novel combinations of features of their invention. Claim 23 claims a flush tool having at least "a first valve configured to independently seal and unseal the proximal end of the first tubular member" and "a second valve configured to independently seal and unseal the distal end of the tubular member." Neither the Fillmore Application nor the Watson Patent, either singly or in combination disclose an arrangement of valves as described by claim 23. Applicants request the consideration and allowance of new claim 23.

#### New Claims 24-26

Dependent claims 24 through 26 claim further features in addition to those found in claim 23. Claim 24 claims "continuous fluid communication" between the first and second tubular members. Claim 25 claims slidably enclosing a catheter throughout the first tubular member. Claim 26 claims sealing about the catheter "without obstructing the catheter." These additional features are not taught by the prior art cited by the Examiner. Applicants request allowance of these dependent claims both as dependent on novel claim 23 and as adding additional novel features.

#### New Claim 27

Claim 27 depends on claim 2 and adds additional features to highlight the novel combination of features of their invention. Claim 27 clarifies that the valves "do not obstruct the catheter when sealably engaged." This feature, in combination with the features of claim 2 are not taught by the prior art. Applicants request allowance of New Claim 27 both as dependent on novel claim 2 and as adding additional novel features.

#### New Claim 28


Claim 28 depends on claim 1 and adds additional features to highlight the novel combination of features of their invention. Claim 28 clarifies that the first and second valves are independently sealable and unsealable. This feature, in combination with the features of claim 1 are not taught by the prior art. Applicants request allowance of New Claim 28 both as dependent on novel claim 1 and as adding additional novel features.

CONCLUSION

In view of the foregoing, Applicants respectfully submit that each of claims 1 through 28 are in condition for allowance. Applicants request reconsideration of each of rejected claims 1 through 22 and consideration of new claims 23 through 28, all for approval. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this Application, if necessary. Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By:   
Paul D. O'Brien  
Registration No. 42,949

Howard Hughes Center  
6060 Center Drive, Tenth Floor  
Los Angeles, CA 90045  
Telephone: (310) 824-5555  
Facsimile: (310) 824-9696

Customer No. 24201